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No. _____

OFFICE OF THE CLERK

In The Supreme Court of the United States

STATE OF NEBRASKA, *et al.*,

Petitioners,

v.

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY,

Respondent.

On Petition For Writ Of Certiorari To The United States Court Of Appeals For The District Of Columbia Circuit

PETITION FOR WRIT OF CERTIORARI

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QUESTION PRESENTED

Whether the United States Environmental Protection Agency exceeded its statutory jurisdiction and authority, abused its discretion, and failed to observe procedures required pursuant to Federal law, when it revised the Maximum Contaminant Level ("MCL") for arsenic without following the procedures set forth in 42 U.S.C. § 300g-1.

PARTIES TO THE PROCEEDING

Petitioners in this case are the State of Nebraska; City of Alliance, Nebraska; City of Beaver City, Nebraska; City of Benkelman, Nebraska; Village of Boelus, Nebraska; Village of Elwood, Nebraska; City of Gering, Nebraska; City of Imperial, Nebraska; City of Stratton, Nebraska; Village of Wauneta, Nebraska; Camano Water Systems; Juniper Beach Water District; and New Utsalady Water Systems (referred to collectively hereinafter as "Petitioners").

Respondent in this case is the United States Environmental Protection Agency ("EPA"), which is the governmental agency responsible for promulgating rules under the Safe Drinking Water Act, 42 U.S.C. §§ 300f, *et seq.* ("SDWA").

The City of Stratton, Nebraska and Juniper Beach Water District did not participate in the briefs in the court below and have presumably abandoned their interest in this case.

CORPORATE DISCLOSURE STATEMENT

The New Utsalady Water System is a nonprofit, customer-owned corporation that supplies water to its members or customers. The Camano Water Systems Association is a non-profit incorporated association that supplies water to its group of member water systems. Neither of these entities have parent companies, nor do any publicly held companies have ownership interests in them. These entities are both affected by the rule disputed in this case.

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OPINION BELOW

The United States Court of Appeals for the District of Columbia Circuit issued its decision in this case on March 8, 2004. This decision was not reported in the Federal Reporter, but is included in the Appendix to this petition.

JURISDICTION STATEMENT

On March 8, 2004, the United States Court of Appeals for the District of Columbia Circuit entered judgment in this case, denying Petitioners' Petition for Review of the Environmental Protection Agency's final rule entitled "Minor Clarification of National Primary Drinking Water Regulation for Arsenic," which was promulgated on March 25, 2003, and appears at 68 Fed. Reg. 14502. This Court has jurisdiction pursuant to 28 U.S.C. § 1254(1).

RELEVANT STATUTES AND REGULATIONS

EPA's final rule entitled "Minor Clarification of National Primary Drinking Water Regulation for Arsenic," which was promulgated on March 25, 2003, and appears at 68 Fed. Reg. 14502, is set forth in the appendix. Pertinent portions of the Safe Drinking Water Act, 42 U.S.C. § 300g-1, are also set forth in the appendix.

STATEMENT OF THE CASE

The SDWA "was enacted to ensure that public water supply systems meet minimum national standards for the protection of public health." *National Wildlife Federation*

v. U.S. E.P.A., 980 F.2d 765, 768 (D.C. Cir. 1992). The SDWA established the legal framework under which EPA promulgates standards for the regulation of drinking water contaminants that may have an adverse effect on health and which are known or anticipated to occur in public water systems. 42 U.S.C. § 300g-1(b)(1)(A).

Chemical contaminants regulated under the SDWA are assigned a MCL, which is the enforceable standard representing the maximum level of that contaminant legally permitted to be delivered to any user of a public water system. In proposing a national primary drinking water regulation that includes a MCL, the SDWA requires the Administrator to publish the proposed rule, seek public comment thereon, and perform a thorough risk and cost analysis thereof. 42 U.S.C. § 300g-1(b)(3)(C). The SDWA also requires EPA to provide a public document containing:

> (i) each population addressed by any estimate of public health effects; (ii) the expected risk or central estimate of risk for the specific populations; (iii) each appropriate upper-bound or lower-bound estimate of risk; (iv) each uncertainty identified in the process of the assessment of public health effects and studies that would assist in resolving the uncertainty; and (v) peer-reviewed studies known to the Administrator that support, are directly relevant to, or fail to support any estimate of public health effects and the methodology used to reconcile inconsistencies in the scientific data.

42 U.S.C. § 300g-1(b)(3)(B). EPA must consult with the National Drinking Water Advisory Council ("NDWAC") and seek comment from the Science Advisory Board ("SAB") during this regulatory process. 42 U.S.C. §§ 300g-1(d-e).

The SDWA requires the Administrator to review and revise, as appropriate, each national primary drinking water regulation at least every six years. 42 U.S.C. § 300g-1(b)(9). While the Administrator may exercise discretion in the timing of regulatory revisions, revision of any national primary drinking water regulation must be promulgated in accordance with the requirements of 42 U.S.C. § 300g-1, as described generally above. *Id.*

On January 22, 2001, EPA published the "National Primary Drinking Water Regulations; Arsenic and Clarifications to Compliance and New Source contaminants Monitoring," 66 Fed. Reg. 6976, 6981 (January 22, 2001) (the "Original Arsenic Rule"), which promulgated an arsenic MCL of .01 mg/L. On March 25, 2003, EPA promulgated the "Minor Clarification of National Primary Drinking Water Regulation for Arsenic," 68 Fed. Reg. 14502 (March 25, 2003) (the "Revised Arsenic Rule"), which amended the Original Arsenic Rule by expressing the arsenic MCL as .010 mg/L, instead of .01 mg/L. In promulgating the Revised Arsenic Rule, it is undisputed that EPA failed to undertake the requirements of 42 U.S.C. § 300g-1.

EPA claimed only to be "revising the rule text in its January 2001 final rule that established the 10 parts per billion arsenic drinking water standard to express the standard as .010 mg/L, in order to clarify the implementation of the original rule." 68 Fed. Reg. at 14502. Petitioners appealed the rule, arguing that any revision of the MCL must be accomplished in accordance with 42 U.S.C. § 300g-1. On appeal, the Court of Appeals for the District of Columbia Circuit characterized EPA's action as a "decision to clarify the technical expression of the arsenic [MCL] by adding an extra zero to the technical expression

of the MCL . . ." The Court cited *Auer v. Robbins*, 519 U.S. 452, 461 (1997), in upholding EPA's actions as an "interpretation of its own regulations" entitled to deference.

REASONS FOR GRANTING THE PETITION

The Court of Appeals for the District of Columbia interpreted the SDWA to allow EPA to revise an MCL without observing the procedures mandated by 42 U.S.C. § 300g-1. This broad construction of the agency's power under the SDWA is an important question of federal law that has not been, but should be, settled by this Court.

Insofar as 42 U.S.C. § 300g-1 expressly provides the sole mechanism for revising an MCL, the Court's interpretation of EPA's action is in direct conflict with this Court's holding that:

> Regardless of how serious the problem an administrative agency seeks to address, however, it may not exercise its authority "in a manner that is inconsistent with the administrative structure that Congress enacted into law." *ETSI Pipeline Project v. Missouri*, 484 U.S. 495, 517, 108 S.Ct. 805, 98 L.Ed.2d 898 (1988). And although agencies are generally entitled to deference in the interpretation of statutes that they administer, a reviewing "court, as well as the agency, must give effect to the unambiguously expressed intent of Congress." *Chevron U.S.A. Inc. v. Natural Resources Defense Council, Inc.*, 467 U.S. 837, 842-843, 104 S.Ct. 2778, 81 L.Ed.2d 694 (1984).

Food and Drug Admin. v. Brown & Williamson Tobacco Corp., 529 U.S. 120, 125-26 (U.S.N.C. 2000).

For these reasons, Petitioners respectfully request that this Court grant Certiorari in this matter.

I. THE COURT ERRED IN ALLOWING EPA TO REVISE THE ARSENIC MCL WITHOUT FOLLOWING THE REQUIREMENTS OF 42 U.S.C. § 300g-1.

The SDWA, 42 U.S.C. § 300g-1, expressly provides procedures for the promulgation, review and/or revision of MCLs, and EPA has no statutory authority beyond that which is granted therein. These procedures include (1) a thorough risk and cost analysis, § 300g-1(b)(3)(C); (2) the publishing of a public document in compliance with § 300g-1(b)(3)(B); and (3) consultation with the NDWAC and the SAB, § 300g-1(d) and (e).

EPA began such a review process when it delayed the Original Arsenic Rule a second time in 2001, but it has yet to complete the reassessment process. *See* "National Primary Drinking Water Regulations; Arsenic and Clarifications to Compliance and New Source Contaminants Monitoring," 66 Fed. Reg. 20580 (April 23, 2001). EPA claims that it "will continue to evaluate the expert analysis, the voluminous public comment received after publication of the final rule, and other relevant information on the arsenic drinking water standard, as part of the next six-year review of drinking water standards, which is to be completed in August of 2008." "Minor Clarification of National Primary Drinking Water Regulation for Arsenic," 67 Fed. Reg. 78203, 78206 (December 23, 2002). Until EPA completes its ongoing reassessment process, it has no authority under the SDWA to revise the arsenic MCL.

The Court erred in finding that EPA has the authority to revise an MCL through a "clarification" rulemaking process, circumventing the SDWA requirements.

> Regardless of how serious the problem an administrative agency seeks to address, however, it may not exercise its authority "in a manner that is inconsistent with the administrative structure that Congress enacted into law." *ETSI Pipeline Project v. Missouri,* 484 U.S. 495, 517, 108 S.Ct. 805, 98 L.Ed.2d 898 (1988). And although agencies are generally entitled to deference in the interpretation of statutes that they administer, a reviewing "court, as well as the agency, must give effect to the unambiguously expressed intent of Congress." *Chevron U.S.A. Inc. v. Natural Resources Defense Council, Inc.*, 467 U.S. 837, 842-843, 104 S.Ct. 2778, 81 L.Ed.2d 694 (1984).

Food and Drug Admin. v. Brown & Williamson Tobacco Corp., 529 U.S. 120, 125-26 (U.S.N.C. 2000).

When Congress employs the word "shall", it often means that "Congress has imposed a mandatory duty upon the subject of the command." *See Forest Guardians v. Babbitt,* 174 F.3d 1178, 1187 (10th Cir. 1999) (citing *United States v. Monsanto,* 491 U.S. at 607, 109 S.Ct. 2657). Congress provided that "revision of a national primary drinking water regulation **shall** be promulgated in accordance with [42 U.S.C. § 300g-1]." 42 U.S.C. § 300g-1(b)(9). Congress did **not** provide that EPA could streamline the process to amend a regulation it adopted that did not have its intended effect.

Inasmuch as the EPA argued, and the Court agreed, that its actions were reasonable to "clarify the implementation" or to "clarify the technical expression" of the

Original Arsenic Rule, the arguments are without merit because EPA had no authority to do so. Congress unambiguously and expressly provided a mechanism for the revision of national primary drinking water regulations in the SDWA. The Court's opinion improperly expanded EPA's authority under the Act by allowing EPA to ignore the administrative structure that Congress enacted into law.

II. THE COURT MISINTERPRETED *AUER V. ROBBINS*, 519 U.S. 452, 461 (1997), INSOFAR AS *AUER* WAS ALLEGED TO PROVIDE THE BASIS FOR DEFERENCE TO EPA'S CONDUCT.

In *Auer*, this Court reviewed an interpretation of the Secretary of Labor whereby he applied an overtime exemption from the Fair Labor Standard Act ("FLSA") to public employees. *Auer*, 519 U.S. 452. The Court stated that "[t]he FLSA grants the Secretary broad authority to "defin[e] and delimi[t]" the scope of the exemption for executive, administrative, and professional employees." *Id.* at 456. Because Congress had not "directly spoken to the precise question at issue," the Court held that it "must sustain the Secretary's approach so long as it is "based on a permissible construction of the statute." *Id.* at 457 (quoting *Chevron*, 467 U.S. at 842-43).

Petitioners find no resemblance of *Auer* to the case at bar. This case involves no "broad authority" from which EPA can determine alternative mechanisms to revise national drinking water standards. In fact, Congress **had** spoken directly to this issue through 42 U.S.C. § 300g-1, and there was no need for EPA to reconstruct what Congress had already dictated. EPA did not interpret a rule in this case. Instead, it **changed** a rule.

The Court admitted that "EPA from the outset interpreted the Final Arsenic Rule as promulgating an MCL of 10ppb, which is also expressible as 10 ug/L and 0.01 mg/L." The Court further stated that "[t]he Rule could hardly be more clear. . . ." Yet the Court upheld EPA's revision or amendment of the MCL as a clarification of a "technical expression" of .01 mg/L to .010 mg/L. The Court appears to be holding that EPA's actions are not a revision under the SDWA. Yet, why does a rule that "could hardly be more clear" need revision, amendment, clarification, etc.? And how is .010 mg/L not a revision from .01 mg/L?

EPA may have the authority to interpret the SDWA and its own regulations when they are vague or when Congress has not "directly spoken" on a disputed issue. EPA's interpretation of the Original Arsenic Rule is not at issue. At issue is EPA's revision of the Rule. Where Congress has provided express procedures to revise such a regulation, EPA cannot ignore them. If EPA's regulation has unintended results, then it should complete its reassessment process and revise the Original Arsenic Rule as provided for by Congress in 42 U.S.C. § 300g-1. If EPA's regulation "could hardly be more clear," as alleged by the court below, then it needs no revision or clarification.

III. THE COURT'S BROAD CONSTRUCTION OF EPA'S POWER UNDER THE SDWA IS AN IMPORTANT QUESTION OF FEDERAL LAW THAT HAS NOT BEEN, BUT SHOULD BE, SETTLED BY THIS COURT.

The SDWA not only provides for enforceable standards that apply to operators of public water systems, but regulations adopted pursuant to the SDWA also have substantial implications under the Comprehensive Environmental

Response, Compensation and Liability Act, 42 U.S.C. §§ 9601-9675, to all companies that produce or dispose of hazardous wastes. *See International Fabricare Institute v. United States E.P.A.*, 972 F.2d 384, 390 (D.C. Cir. 1992). The Act also imposes primary enforcement responsibility upon the states. *See* 42 U.S.C. § 300g-2. The Act's regulations clearly have important nationwide implications.

The SDWA expressly provides for extensive procedural mechanisms for the promulgation of national primary drinking water standards, and further provides for timely review and revision of those standards. These procedures include public review and comment and judicial review. The only court in the United States from which these regulations may be reviewed, though, is the United States Court of Appeals for the District of Columbia Circuit. 42 U.S.C. § 300j-7. And petitions objecting to such regulations must be filed within 45 days of their promulgation. *Id.*

There is no trial court or other intermediate court to provide for a "checks and balances" on the court's interpretations of regulations adopted pursuant to the SDWA. Thus, unless this Supreme Court accepts certiorari to review a disputed national primary drinking water standard, then the United States Court of Appeals for the District of Columbia Circuit performs the only review of the standard being appealed. In this case, wherein both EPA and the court below erred on an important federal issue, it is important that this Court grant review.

If the Court's decision is upheld in this case, then EPA can continue to disregard the provisions of the SDWA and "clarify" regulations instead of "revising" them pursuant to the statutes. Unlike the lengthy reassessment process called for in 42 U.S.C. § 300g-1, the streamlined process of

clarification is likely to escape the attention of many persons or organizations that are affected by the regulations; and Congress's provisions for administrative and judicial review will be meaningless. The extensive implications of EPA's expanded authority make this an important matter of federal law that should be reviewed by this Court.

CONCLUSION

For the foregoing reasons, this petition for a writ of certiorari should be granted.

Respectfully submitted,

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Dated: June 4, 2004

United States Court of Appeals
FOR THE DISTRICT OF COLUMBIA CIRCUIT

No. 03-1132 **September Term, 2003**

State of Nebraska, et al.
Petitioners

v.

United States Environmental Protection
Respondent

On Petition for Review of Orders of the Environmental Protection Agency

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Before: GINSBURG, *Chief Judge*, and HENDERSON, *Circuit Judge*, and WILLIAMS, *Senior Circuit Judge*.

JUDGMENT

(Filed Mar. 8, 2004)

This cause was considered on the record from the agency and on the briefs of the parties. It is

ORDERED AND ADJUDGED that Nebraska's petition for review of the Minor Clarification Rule is denied. The EPA's decision to clarify the technical expression of the arsenic Maximum Contaminant Level (MCL) by adding an extra zero to the technical expression of the MCL as measured in mg/L does not alter the substance of the 10 parts per billion MCL established in the Final Arsenic Rule. The EPA from the outset interpreted the

Final Arsenic Rule as promulgating an MCL of 10 ppb, which is also expressible as 10 µg/L and as 0.01 mg/L. *See, e.g., National Primary Drinking Water Regulations; Arsenic and Clarifications to Compliance and New Source Contaminants Monitoring,* 66 Fed. Reg. 6,976 at 6,981 (2001) ("the enforceable MCL is 0.01 mg/L, which is the same as 10 micrograms per liter (µg/L) or 10 parts per billion (ppb)"), 7020 ("EPA is today promulgating a final arsenic MCL of 10 µg/L"). We defer to the EPA's interpretation of its own regulations unless that interpretation is "plainly erroneous" or "inconsistent with the regulation," *Auer v. Robbins,* 519 U.S. 452, 461 (1997), which the interpretation in this case is not.

Nebraska's argument that the Minor Clarification Rule established a new MCL for arsenic is based upon the EPA's reference in the Final Arsenic Rule to a 1981 guidance document regarding the rounding of reported contaminant levels, which states that reported levels "should be in a form containing the same number of significant digits as the MCL." *Id.* Notwithstanding the 1981 guidance, however, by the plain terms of the Final Arsenic Rule arsenic results must be "reported to the nearest 0.001 mg/L." 40 C.F.R. § 141.23(i)(4); *see also* 66 Fed. Reg. at 7,034/1. The Rule could hardly be more clear, considering that an example offered in the Rule states, "an analytical result for arsenic of 0.0105 mg/L would round off to 0.011 mg/L, while a result of 0.0104 mg/L would round off to 0.010 mg/L." 66 Fed. Reg. at 7,034/1. Therefore, the EPA's reference to its 1981 guidance document does not demonstrate the EPA promulgated a new arsenic MCL in the Minor Clarification Rule.

Assuming Nebraska did not waive its argument regarding the Unfunded Mandates Reform Act and the

Regulatory Flexibility Act, because the Minor Clarification Rule did not alter the MCL established in the Final Arsenic Rule, the EPA was not obliged to provide additional analyses pursuant to either Act. The agency had already performed those analyses for the 10 ppb MCL and had already included them in the Final Arsenic Rule.

Pursuant to D.C. Circuit Rule 36, this disposition will not be published. The clerk is directed to withhold issuance of the mandate herein until seven days after resolution of any timely petition for rehearing or petition for rehearing en banc. *See* Fed. R. App. P. 41(b); D.C. Cir. Rule 41.

Per Curiam
FOR THE COURT:
Mark J. Langer, Clerk

BY: /s/ Michael C. McGrail
Michael C. McGrail
Deputy Clerk

42 U.S.C.A. § 300g-1. National drinking water regulations

(a) National primary drinking water regulations; maximum contaminant level goals; simultaneous publication of regulations and goals

(1) Effective on June 19, 1986, each national interim or revised primary drinking water regulation promulgated under this section before June 19, 1986, shall be deemed to be a national primary drinking water regulation under subsection (b) of this section. No such regulation shall be required to comply with the standards set forth in subsection (b)(4) of this section unless such regulation is amended to establish a different maximum contaminant level after June 19, 1986.

. . .

(b) Standards

(1) Identification of contaminants for listing

. . .

(E) Regulation

For each contaminant that the Administrator determines to regulate under subparagraph (B), the Administrator shall publish maximum contaminant level goals and promulgate, by rule, national primary drinking water regulations under this subsection. The Administrator shall propose the maximum contaminant level goal and national primary drinking water regulation for a contaminant not later than 24 months after the determination to regulate under subparagraph (B), and may publish such proposed regulation concurrent with the determination to regulate. The Administrator shall publish a maximum

contaminant level goal and promulgate a national primary drinking water regulation within 18 months after the proposal thereof. The Administrator, by notice in the Federal Register, may extend the deadline for such promulgation for up to 9 months.

. . .

(3) Risk assessment, management, and communication

(A) Use of science in decisionmaking

In carrying out this section, and, to the degree that an Agency action is based on science, the Administrator shall use –

(i) the best available, peer-reviewed science and supporting studies conducted in accordance with sound and objective scientific practices; and

(ii) data collected by accepted methods or best available methods (if the reliability of the method and the nature of the decision justifies use of the data).

(B) Public information

In carrying out this section, the Administrator shall ensure that the presentation of information on public health effects is comprehensive, informative, and understandable. The Administrator shall, in a document made available to the public in support of a regulation promulgated under this section, specify, to the extent practicable –

(i) each population addressed by any estimate of public health effects;

(ii) the expected risk or central estimate of risk for the specific populations;

(iii) each appropriate upper-bound or lower-bound estimate of risk;

(iv) each significant uncertainty identified in the process of the assessment of public health effects and studies that would assist in resolving the uncertainty; and

(v) peer-reviewed studies known to the Administrator that support, are directly relevant to, or fail to support any estimate of public health effects and the methodology used to reconcile inconsistencies in the scientific data.

(C) Health risk reduction and cost analysis

(i) Maximum contaminant levels

When proposing any national primary drinking water regulation that includes a maximum contaminant level, the Administrator shall, with respect to a maximum contaminant level that is being considered in accordance with paragraph (4) and each alternative maximum contaminant level that is being considered pursuant to paragraph (5) or (6)(A), publish, seek public comment on, and use for the purposes of paragraphs (4), (5), and (6) an analysis of each of the following:

(I) Quantifiable and nonquantifiable health risk reduction benefits for which there is a factual basis in the rulemaking record to conclude that such benefits are likely to occur as the result of treatment to comply with each level.

(II) Quantifiable and nonquantifiable health risk reduction benefits for which there is a factual basis in the rulemaking record to conclude that such benefits are

likely to occur from reductions in co-occurring contaminants that may be attributed solely to compliance with the maximum contaminant level, excluding benefits resulting from compliance with other proposed or promulgated regulations.

(III) Quantifiable and nonquantifiable costs for which there is a factual basis in the rulemaking record to conclude that such costs are likely to occur solely as a result of compliance with the maximum contaminant level, including monitoring, treatment, and other costs and excluding costs resulting from compliance with other proposed or promulgated regulations.

(IV) The incremental costs and benefits associated with each alternative maximum contaminant level considered.

(V) The effects of the contaminant on the general population and on groups within the general population such as infants, children, pregnant women, the elderly, individuals with a history of serious illness, or other subpopulations that are identified as likely to be at greater risk of adverse health effects due to exposure to contaminants in drinking water than the general population.

(VI) Any increased health risk that may occur as the result of compliance, including risks associated with co-occurring contaminants.

(VII) Other relevant factors, including the quality and extent of the information, the uncertainties in the analysis supporting

subclauses (I) through (VI), and factors with respect to the degree and nature of the risk.

(ii) Treatment techniques

When proposing a national primary drinking water regulation that includes a treatment technique in accordance with paragraph (7)(A), the Administrator shall publish and seek public comment on an analysis of the health risk reduction benefits and costs likely to be experienced as the result of compliance with the treatment technique and alternative treatment techniques that are being considered, taking into account, as appropriate, the factors described in clause (i).

(iii) Approaches to measure and value benefits

The Administrator may identify valid approaches for the measurement and valuation of benefits under this subparagraph, including approaches to identify consumer willingness to pay for reductions in health risks from drinking water contaminants.

. . .

(4) Goals and standards

(A) Maximum contaminant level goals

Each maximum contaminant level goal established under this subsection shall be set at the level at which no known or anticipated adverse effects on the health of persons occur and which allows an adequate margin of safety.

(B) Maximum contaminant levels

Except as provided in paragraphs (5) and (6), each national primary drinking water regulation for a contaminant for which a maximum contaminant level goal is established under this subsection shall specify a maximum contaminant level for such contaminant which is as close to the maximum contaminant level goal as is feasible.

(C) Determination

At the time the Administrator proposes a national primary drinking water regulation under this paragraph, the Administrator shall publish a determination as to whether the benefits of the maximum contaminant level justify, or do not justify, the costs based on the analysis conducted under paragraph (3)(C).

(D) Definition of feasible

For the purposes of this subsection, the term "feasible" means feasible with the use of the best technology, treatment techniques and other means which the Administrator finds, after examination for efficacy under field conditions and not solely under laboratory conditions, are available (taking cost into consideration). For the purpose of this paragraph, granular activated carbon is feasible for the control of synthetic organic chemicals, and any technology, treatment technique, or other means found to be the best available for the control of synthetic organic chemicals must be at least as effective in controlling synthetic organic chemicals as granular activated carbon.

(E) Feasible technologies

(i) In general

Each national primary drinking water regulation which establishes a maximum contaminant level shall list the technology, treatment techniques, and other means which the Administrator finds to be feasible for purposes of meeting such maximum contaminant level, but a regulation under this subsection shall not require that any specified technology, treatment technique, or other means be used for purposes of meeting such maximum contaminant level.

. . .

(9) Review and revision

The Administrator shall, not less often than every 6 years, review and revise, as appropriate, each national primary drinking water regulation promulgated under this subchapter. Any revision of a national primary drinking water regulation shall be promulgated in accordance with this section, except that each revision shall maintain, or provide for greater, protection of the health of persons.

(c) Secondary regulations; publication of proposed regulations; promulgation; amendments

The Administrator shall publish proposed national secondary drinking water regulations within 270 days after December 16, 1974. Within 90 days after publication of any such regulation, he shall promulgate such regulation with such modifications as he deems appropriate. Regulations under this subsection may be amended from time to time.

(d) Regulations; public hearings; administrative consultations

Regulations under this section shall be prescribed in accordance with section 553 of Title 5 (relating to rulemaking), except that the Administrator shall provide opportunity for public hearing prior to promulgation of such regulations. In proposing and promulgating regulations under this section, the Administrator shall consult with the Secretary and the National Drinking Water Advisory Council.

(e) Science Advisory Board comments

The Administrator shall request comments from the Science Advisory Board (established under the Environmental Research, Development, and Demonstration Act of 1978) prior to proposal of a maximum contaminant level goal and national primary drinking water regulation. The Board shall respond, as it deems appropriate, within the time period applicable for promulgation of the national primary drinking water standard concerned. This subsection shall, under no circumstances, be used to delay final promulgation of any national primary drinking water standard.

Federal Register/Vol. 68, No. 57/Tuesday, March 25, 2003/
Rules and Regulations at **14502**

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 141

[FRL-7472-5]

Minor Clarification of National Primary Drinking Water Regulation for Arsenic

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: Today, EPA is revising the rule text in its January 2001 final rule that established the 10 parts per billion arsenic drinking water standard to express the standard as 0.010 mg/L, in order to clarify the implementation of the original rule.

DATES: This regulation is effective April 24, 2003. For purposes of judicial review, this final rule is promulgated as of 1 p.m. Eastern Time on March 25, 2003.

ADDRESSES: The official public docket for this rule is located at EPA's Water Docket, in the EPA Docket Center (EPA/DC), EPA West, Rm B102, 1301 Constitution Avenue, NW., Washington, DC.

FOR FURTHER INFORMATION CONTACT: For general information contact the EPA Safe Drinking Water Hotline at (800) 426-4791. The Hotline operates Monday through Friday, excluding Federal holidays, from 9 a.m. to 5:30 p.m. ET. For technical information contact, Richard Reding, Office of Ground Water and Drinking Water (MC-4607M),

U.S. Environmental Protection Agency, 1200 Pennsylvania Avenue, NW., Washington DC 20460, (202) 564-4656, email: *Reding.Richard@epa.gov*.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Who Is Regulated by This Action?

Entities potentially regulated by this regulation are public water systems (PWSs). All community and non-transient non-community water systems must comply with the revised arsenic drinking water standard beginning on January 23, 2006. A community water system (CWS) means a public water system which serves at least 15 service connections used by year-round residents or regularly serves at least 25 year-round residents. Non-transient non-community water system (NTNCWS) means a public water system that is not a community water system and that regularly serves at least 25 of the same persons over 6 months per year. Primacy States are required to revise their programs to adopt the new arsenic standard by January 22, 2003 (unless an extension has been granted). Categories and entities potentially regulated by this action include the following:

Category	Examples of potentially regulated entities
State, Tribal and Local Government	State, Tribal or local government-owned/operated water supply systems using ground water, surface water or mixed ground water and surface water.
Federal Government	Federally owned/operated community water supply systems using ground water, surface water or mixed ground water and surface water.
Industry	Privately owned/operated community water supply systems using ground water, surface water or mixed ground water and surface water.

This table is not intended to be exhaustive, but rather provides a guide for readers regarding entities likely to be regulated by this action. This table lists the types of entities that EPA is now aware could potentially be regulated by this action. Other types of entities not listed in the table could also be regulated. To determine whether your facility is regulated by this action, you should carefully examine the applicability criteria in Sec. Sec. 141.11 and 141.62 of title 40 of the Code of Federal Regulations. If you have questions regarding the applicability of this action to a particular entity, consult the person listed in the preceding FOR FURTHER INFORMATION CONTACT section.

B. How Can I Get Copies of This Document and Other Related Information?

1. *Docket.* EPA has established an official public docket for this action under Docket ID No. OW-2002-0057. The official public docket consists of the documents specifically referenced in this action, any public comments received, and other information related to this action. Although a part of the official docket, the public docket does not include Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. The official public docket is the collection of materials that is available for public viewing at the Water Docket in the EPA Docket Center, (EPA/DC), EPA West, Room B102, 1301 Constitution Ave., NW., Washington, DC. The EPA Docket Center Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room is (202) 566-1744, and the telephone number for the Water Docket is (202) 566-2426. For access to docket material, please call (202) 566-2426 to schedule an appointment.

2. Electronic Access. You may access this **Federal Register** document electronically through the EPA Internet under the "Federal Register" listings at *http://www.epa.gov/fedrgstr/*.

An electronic version of the public docket is available through EPA's electronic public docket and comment system, EPA Dockets. You may use EPA Dockets at *http://www.epa.gov/edocket/* to view public comments, to access the index listing of the contents of the official public docket, and to access those documents in the public docket that are available electronically. Although not all docket materials may be available electronically, you may still

access any of the publicly available docket materials through the docket facility identified in section I.B.1. Once in the system, select "search," then key in the appropriate docket identification number.

II. What is EPA's Statutory Authority for This Final Rule?

SDWA section 1412(b)(12)(A) required EPA to publish a revised arsenic standard. On January 22, 2001, EPA published a final rule revising the existing arsenic drinking water standard from 50 parts per billion (ppb) to 10 ppb, with a compliance date of January 23, 2006 (66 FR 6976-7066). Under EPA's regulations at 40 CFR 142.12, States that wish to maintain primary enforcement responsibility for drinking water standards must revise their programs to adopt new or revised Federal regulations. Today's final rule clarifies one issue raised by stakeholders concerning the standard published in January 2001.

III. What Is EPA Doing Today?

Today, EPA is revising the rule text to express the new arsenic maximum contaminant level (MCL) as 0.010 mg/L instead of 0.01 mg/L. EPA is making this minor regulatory amendment in response to a concern raised by a number of States and other stakeholders that State laws adopting the Federal arsenic standard as 0.01 mg/L might allow rounding of monitoring results above 0.01 mg/L so that the effective standard (in consideration of rounding of results) would be 0.014 mg/L (or 14 ppb), not 0.010 mg/L (10 ppb). These States and other stakeholders suggested that the rule text be revised to clarify the rounding issue and avoid the potential for confusion about how to evaluate compliance monitoring

results that are greater than 10 ppb. In response, EPA solicited public comment on today's amendment in a proposed rulemaking that was published on December 23, 2002 (67 FR 78203). Although EPA considers this amendment to be a minor clarification of the intent of the January 2001 rule, EPA chose to conduct a formal rulemaking to provide a full opportunity for public comment with respect to the rounding issue.

IV. Summary of Public Comments on Today's Regulatory Change

The comment period on the December 2002 proposed rule closed on January 22, 2003. Most commenters strongly supported today's action; other commenters indicated a concern. A summary of these comments follows. The comments and EPA's responses are included in the Docket for today's final rule.

In expressing support for making today's clarification, some commenters requested extensions of the compliance deadlines that were specified in the January 2001 rule. EPA does not agree that an extension of the compliance deadline is necessary or appropriate. The EPA Administrator is firmly committed to maintaining the January 23, 2006, compliance date for a new arsenic standard (66 FR 20581, April 23, 2001). EPA also has been clear that the 2006 compliance deadline applies to all systems with arsenic levels above 10 ppb. As noted in the December 2002 proposal to clarify the rule text, every aspect of the existing final rule and all analys s supporting the rule establish 10 ppb as the new arsenic standard. In addition, EPA made clear in several contexts that rounding down monitoring results in the range of 11 to 14 ppb to 10 ppb

was not allowed under the rule (*e.g.*, in a guidance memorandum (EPA 2002a), in EPA's document "Implementation Guidance for the Arsenic Rule" (EPA 2002b), and in the training conducted by EPA (EPA 2002c) on the rule since its issuance). For systems that may need additional time to come into compliance with the rule for cost or technical reasons, there is an exemption process under SDWA section 1416 under which eligible systems may receive additional time, if necessary. This process was fully addressed in the January 22, 2001, rule (66 FR 6988).

In expressing support for making today's clarification, some commenters also requested extensions of the deadlines to submit revised arsenic primacy packages that were specified in the January 2001 rule. With respect to the deadline for States or Tribes to submit primacy revision packages, because the Agency has been clear that no rounding is permitted under the Federal rule, State programs that allow systems to round compliance monitoring results that are greater than 10 ppb down to 10 ppb will not be approved. The provisions in 40 CFR 142.12, for EPA (at the EPA regional office level) to grant extensions of the two-year period for adoption of the revised arsenic regulation as appropriate on a case-by-case basis, are sufficient to accommodate the commenters' requests for additional time for submission or revision of primacy packages. EPA notes that States routinely request and receive extensions of their primacy deadline.

One commenter believes that State and local governments should have maximum flexibility in implementing Federal regulatory requirements. The commenter does not support today's clarification because it limits the ability of State and local governments to mitigate adverse financial effects of the arsenic standard, especially for rural or low

income systems. The commenter suggested States should have the flexibility to use public education at systems where arsenic levels are between 10 and 14 ppb instead of requiring compliance at 10 ppb. However, EPA does not agree that the final arsenic rule, as promulgated in January 2001, would allow the use of public education rather than compliance with the 10 ppb standard at any system where arsenic levels exceed the 10 ppb standard and are between 10 and 14 ppb. As EPA discussed in the January 22, 2001, preamble, EPA is aware of the impact that the new arsenic standard will have on certain systems. As discussed in the January 2001 final rule (67 FR 6992), the Agency is implementing many financial and technical assistance actions to mitigate this impact with an emphasis on assisting small systems. In addition, EPA notes that there are certain flexibilities already built into the statutory and regulatory structure. For example, the final arsenic rule discusses the flexibility for small systems to receive an extension of up to nine years to comply with the new arsenic standard through the exemption process provided in SDWA section 1416.

One commenter submitted comments that were not relevant to the December 2002 proposal to revise the arsenic rule text to express the 10 ppb standard as 0.010 mg/L instead of 0.01 mg/L. EPA is not addressing these comments because, in the December 2002 proposal, EPA clearly informed readers that EPA was not requesting and would not respond to comment on any other issue associated with the arsenic standard or its implementation. As noted in the December 2002 proposal and in the April 17, 2002, (67 FR 19037) announcement of the preliminary results of EPA's review of existing drinking water standards, EPA will continue to evaluate the expert analysis,

the public comment received after publication of the final rule, and other relevant information on the arsenic drinking water standard, as part of the next six-year review of drinking water standards, which is to be completed in August of 2008.

V. Administrative Requirements

A. Executive Order 12866: Regulatory Planning and Review

Under Executive Order 12866, (58 FR 51735 (October 4, 1993)) the Agency must determine whether the regulatory action is "significant" and therefore subject to OMB review and the requirements of the Executive Order. The Order defines "significant regulatory action" as one that is likely to result in a rule that may:

(1) Have an annual effect on the economy of $100 million or more or adversely affect in a material way the economy, a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, or Tribal governments or communities;

(2) create a serious inconsistency or otherwise interfere with an action taken or planned by another agency;

(3) materially alter the budgetary impact of entitlements, grants, user fees, or loan programs or the rights and obligations of recipients thereof; or

(4) raise novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in the Executive Order.

It has been determined that this final rule is not a "significant regulatory action" under the terms of Executive Order 12866 and is therefore not subject to OMB review.

B. Paperwork Reduction Act

This action does not impose any new information collection burden under the provisions of the Paperwork Reduction Act, 44 U.S.C. 3501 *et.seq.* This final rule merely clarifies the way the 10 ppb MCL for arsenic is expressed in regulatory text.

Burden means the total time, effort, or financial resources expended by persons to generate, maintain, retain, or disclose or provide information to or for a Federal agency. This includes the time needed to review instructions; develop, acquire, install, and utilize technology and systems for the purposes of collecting, validating, and verifying information, processing and maintaining information, and disclosing and providing information; adjust the existing ways to comply with any previously applicable instructions and requirements; train personnel to be able to respond to a collection of information; search data sources; complete and review the collection of information; and transmit or otherwise disclose the information.

An agency may not conduct or sponsor, and a person is not required to respond to a collection of information unless it displays a currently valid OMB control number. The OMB control numbers for EPA's regulations are listed in 40 CFR part 9 and 48 CFR chapter 15.

C. Regulatory Flexibility Act

The Regulatory Flexibility Act (RFA) generally requires an agency to prepare a regulatory flexibility analysis of any rule subject to notice and comment rulemaking requirements under the Administrative Procedure Act or any other statute unless the Agency certifies that the rule will not have a significant economic impact on a substantial number of small entities. Small entities include small businesses, small organizations, and small government jurisdictions.

The RFA provides default definitions for each type of small entity. It also authorizes an agency to use alternative definitions for each category of small entity, "which are appropriate to the activities of the agency" after proposing the alternative definition(s) in the **Federal Register** and taking comment. 5 U.S.C. 601(3)-(5). In addition to the above, to establish an alternative small business definition, agencies must consult with the Small Business Administration's (SBA's) Chief Counsel for Advocacy.

For purposes of assessing the impacts of today's final rule on small entities, EPA considered small entities to be public water systems serving 10,000 or fewer persons. This is the cut-off level specified by Congress in the 1996 Amendments to the Safe Drinking Water Act for small system flexibility provisions. In accordance with the RFA requirements, EPA proposed using this alternative definition in the **Federal Register**, (63 FR 7620, February 13, 1998), requested public comment, consulted with the Small Business Administration (SBA), and expressed its intention to use the alternative definition for regulatory flexibility assessments under the RFA for all future drinking water

regulations in the Consumer Confidence Reports regulation (63 FR 44511, August 19, 1998). As stated in that final rule, the alternative definition would be applied to this regulation.

This final rule imposes no cost on any entities over and above those imposed by the final arsenic rule, because that rule was developed, costed, and evaluated as 10 ppb. This final rule merely clarifies the way the 10 ppb MCL is expressed in regulatory text. Therefore, after considering the economic impacts of today's final rule on small entities, I certify that this action will not have a significant economic impact on a substantial number of small entities.

D. Unfunded Mandates Reform Act

Title II of the Unfunded Mandates Reform Act of 1995 (UMRA), Public Law 104-4, establishes requirements for Federal agencies to assess the effects of their regulatory actions on State, local, and Tribal governments and the private sector. Under section 202 of the UMRA, EPA generally must prepare a written statement, including a cost-benefit analysis, for proposed and final rules with "Federal mandates" that may result in expenditures to State, local, and Tribal governments, in the aggregate, or to the private sector, of $100 million or more in any one year. Before promulgating an EPA rule for which a written statement is needed, section 205 of the UMRA generally requires EPA to identify and consider a reasonable number of regulatory alternatives and adopt the least costly, most cost-effective or least burdensome alternative that achieves the objectives of the rule. The provisions of section 205 do not apply when they are inconsistent with applicable law. Moreover, section 205 allows EPA to adopt

an alternative other than the least costly, most cost-effective or least burdensome alternative if the Administrator publishes with the final rule an explanation why that alternative was not adopted.

Before EPA establishes any regulatory requirements that may significantly or uniquely affect small governments, including Tribal governments, it must have developed under section 203 of the UMRA a small government agency plan. The plan must provide for notifying potentially affected small governments, enabling officials of affected small governments to have meaningful and timely input in the development of EPA regulatory proposals with significant Federal intergovernmental mandates, and informing, educating, and advising small governments on compliance with the regulatory requirements.

Today's final rule contains no Federal mandates (under the regulatory provisions of Title II of the UMRA) for State, local, or Tribal governments or the private sector. This final rule imposes no enforceable duty on any State, local or Tribal governments or the private sector. This final rule would not change the costs to State, local, or Tribal governments as estimated in the final arsenic rule, because that rule was developed, costed, and evaluated as 10 ppb, and this final rule merely clarifies the way the 10 ppb MCL is expressed in regulatory text. Thus, today's final rule is not subject to the requirements of sections 202 and 205 of the UMRA.

For the same reason, EPA has determined that this final rule contains no regulatory requirements that might significantly or uniquely affect small governments. Thus, today's final rule is not subject to the requirements of section 203 of the UMRA.

E. Executive Order 13132: Federalism

Executive Order 13132, entitled "Federalism" (64 FR 43255, August 10, 1999), requires EPA to develop an accountable process to ensure "meaningful and timely input by State and local officials in the development of regulatory policies that have federalism implications." "Policies that have federalism implications" is defined in the Executive Order to include regulations that have "substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government."

This final rule does not have Federalism implications. It will not have substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government, as specified in Executive Order 13132. There is no cost to State and local governments, and this final rule does not preempt State law. This final rule imposes no cost on any State, or local governments over and above those imposed by the final arsenic rule because that rule was developed, costed, and evaluated as 10 ppb. This final rule merely clarifies the way the 10 ppb MCL is expressed in regulatory text. Thus, Executive Order 13132 does not apply to this rule. In the spirit of Executive Order 13132, and consistent with EPA policy to promote communications between EPA and State and local governments, EPA specifically solicited comment on the proposed rule from State and local officials. EPA received no comment on Federalism issues from State or local officials.

F. Executive Order 13175: Consultation and Coordination With Indian Tribal Governments

Executive Order 13175, entitled "Consultation and Coordination with Indian Tribal Governments" (65 FR 67249, (November 9, 2000)), requires EPA to develop an accountable process to ensure "meaningful and timely input by tribal officials in the development of regulatory policies that have tribal implications." "Policies that have tribal implications" is defined in the Executive Order to include regulations that have "substantial direct effects on one or more Indian tribes, on the relationship between the Federal Government and the Indian tribes, or on the distribution of power and responsibilities between the Federal government and Indian tribes."

This final rule does not have Tribal implications. It will not have substantial direct effects on Tribal governments, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes, as specified in Executive Order 13175. There is no cost to Tribal governments, and this final rule does not preempt Tribal law. This final rule imposes no cost on any Tribal government over and above those imposed by the final arsenic rule because that rule was developed, costed and evaluated as 10 ppb. This final rule merely clarifies the way the 10 ppb MCL is expressed in regulatory text. Thus, Executive Order 13175 does not apply to this rule. In the spirit of Executive Order 13175, and consistent with EPA policy to promote communications between EPA and Tribal governments, EPA specifically solicited comment on the proposed rule from Tribal officials. EPA received no comment from Tribal officials.

G. Executive Order 13045: Protection of Children From Environmental Health Risks and Safety Risks

Executive Order 13045: "Protection of Children from Environmental Health Risks and Safety Risks" (62 FR 19885, April 23, 1997) applies to any rule that: (1) is determined to be economically significant as defined under Executive Order 12866, and (2) concerns an environmental health or safety risk that EPA has reason to believe may have a disproportionate effect on children. If the regulatory action meets both criteria, the Agency must evaluate the environmental health or safety effects of the planned rule on children, and explain why the planned regulation is preferable to other potentially effective and reasonably feasible alternatives considered by the Agency.

This final rule is not subject to Executive Order 13045 because it is not economically significant as defined in Executive Order 12866, and because it does not concern an environmental health or safety risk that EPA has reason to believe may have a disproportionate effect on children. This final rule merely clarifies the way the 10 ppb MCL is expressed in regulatory text.

H. Executive Order 13211: Actions That Significantly Affect Energy Supply, Distribution, or Use

This final rule is not subject to Executive Order 13211, "Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use" (66 FR 28355 (May 22, 2001)) because it is not a significant regulatory action under Executive Order 12866.

I. National Technology Transfer and Advancement Act

As noted in the December 2002 proposed rule, section 12(d) of the National Technology Transfer and Advancement Act of 1995 (NTTAA), Public Law 104-113, section 12(d) (15 U.S.C. 272 note), directs EPA to use voluntary consensus standards in its regulatory activities unless to do so would be inconsistent with applicable law or otherwise impractical. Voluntary consensus standards are technical standards (*e.g.*, material specifications, test methods, sampling procedures, and business practices) that are developed or adopted by voluntary consensus standards bodies. The NTTAA directs EPA to provide Congress, through OMB, explanations when the Agency decides not to use available and applicable voluntary consensus standards.

This action does not involve technical standards. Therefore, EPA did not consider the use of any voluntary consensus standards.

J. Congressional Review Act

The Congressional Review Act, 5 U.S.C. 801 *et seq.*, as added by the Small Business Regulatory Enforcement Fairness Act of 1996, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report, which includes a copy of the rule, to each House of the Congress and to the Comptroller General of the United States. EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of the rule in the **Federal Register**. A major rule

cannot take effect until 60 days after it is published in the **Federal Register**. This action is not a "major rule" as defined by 5 U.S.C. 804(2). This rule will be effective on April 24, 2003.

VI. References

EPA 2002a "Calculation of Compliance for the New Arsenic MCL", Cynthia C. Dougherty memorandum, January 25, 2002.

EPA 2002b "Implementation Guidance for the Arsenic Rule", EPA16-K-02-018, August 2002, Section I-A.4, and Figure II-1.

EPA 2002c "Arsenic and Clarifications to Compliance and New Source Contaminants Monitoring", Albuquerque, New Mexico, April 15-16, 2002, pp. 8-9.

List of Subjects for 40 CFR Part 141

Environmental protection, Chemicals, Indians-lands, Intergovernmental relations, Radiation protection, Reporting and recordkeeping requirements, Water supply.

Dated: March 19, 2003.

Christine Todd Whitman,

Administrator.

For the reasons set out in the preamble, title 40, chapter 1 of the Code of Federal Regulations is amended as follows:

PART 141 – NATIONAL PRIMARY DRINKING WATER REGULATIONS

1. The authority citation for part 141 continues to read as follows:

Authority: 42 U.S.C. 300f, 300g-1, 300g-2, 300g-3, 300g-4, 300g-5, 300g-6, 300j-4, 300j-9, and 300j-11.

2. Section 141.23 is amended:

a. By revising the entry for arsenic in the table in (a)(4)(i).

b. By revising footnote 15 to the table in (k)(1).

The revisions read as follows:

§ 141.23 Inorganic chemical sampling and analytical requirements.

* * *

(a) * * *

(4) * * *

(i) * * *

DETECTION LIMITS FOR INORGANIC CONTAMINANTS

Contaminant	MCL (mg/l)	Methodology	Detection limit (mg/1)
	*	* *	
Arsenic.....	0.010[6]	Atomic Absorption; Furnace.....	0.001
		Atomic Absorption; Platform – Stabilized Temperature.....	0.0005[7]

Atomic Absorption; Gaseous Hydride	0.001
ICP-Mass Spectrometry....	0.0014[8]

[6] The value for arsenic is effective January 23, 2006. Until then, the MCL is 0.05 mg/L.

[7] The MDL reported for EPA Method 200.9 (Atomic Absorption; Platform – Stabilized Temperature) was determined using a 2x concentration step during sample digestion. The MDL determined for samples analyzed using direct analyses (*i.e.*, no sample digestion) will be higher. Using multiple depositions, EPA 200.9 is capable of obtaining MDL of 0.0001 mg/L.

[8] Using selective ion monitoring, EPA Method 200.8 (ICP-MS) is capable of obtaining a MDL of 0.0001 mg/L.

* * *

(k) * * *

(l) * * *

[15] Starting January 23, 2006, analytical methods using the ICP-AES technology, may not be used because the detection limits for these methods are 0.008 mg/L or higher. This restriction means that the two ICP-AES methods (EPA Method 200.7 and SM 3120 B) approved for use for the MCL of 0.05 mg/L may not be used for compliance determinations for the revised MCL of 0.010 mg/L. However, prior to January 23, 2006, systems may have compliance samples analyzed with these less sensitive methods.

* * *

3. Section 141.62(b) is amended by revising the entry "(16)" for arsenic in the table to read as follows:

§ 141.62 Maximum contaminant levels for inorganic contaminants.

* * *

(b) * * *

Contaminant	MCL (mg/l)
* * *	
(16) Arsenic.....	0.010
* * *	

Subpart O – [Amended]

4. Amend Sec. 141.154 by revising paragraphs (b) introductory text and (f) to read as follows:

§ 141.154 Required additional health information.

* * *

(b) Ending in the report due by July 1, 2001, a system which detects arsenic at levels above 0.025 mg/L, but below the 0.05 mg/L, and beginning in the report due by July 1, 2002, a system that detects arsenic above 0.005 mg/L and up to and including 0.010 mg/L:

* * *

(f) Beginning in the report due by July 1, 2002, and ending January 22, 2006, a community water system that detects arsenic above 0.010 mg/L and up to and including 0.05 mg/L must include the arsenic health effects language prescribed by Appendix A to Subpart O of this part.

5. Amend Appendix A to Subpart O by revising the entry for arsenic under "Inorganic contaminants:" to read as follows:

APPENDIX A TO SUBPART O – REGULATED CONTAMINANTS

Contaminant (Units)	Traditional MCL in mg/L	To convert for CCR multiply by	MCL in CCR units	MCLG	Major sources in drinking water	Health effects language
*	*	*	*	*	*	*
Inorganic contaminants						
*	*	*	*	*	*	*
Arsenic (ppb)	[1]0.010	1000	[1]10.	[1]0	Erosion of natural deposits; Runoff from orchards; Runoff from glass and electronics production wastes.	Some people who drink water containing arsenic in excess of the MCL over many years could experience skin damage or problems with their circulatory system, and may have an increased risk of getting cancer.
*	*	*	*	*	*	*

[1] These arsenic values are effective January 23, 2006. Until then, the MCL is 0.05 mg/L and there is no MCLG.

Subpart Q – [Amended]

6. Amend Appendix B to Subpart Q by revising entry "9. Arsenic" under "C. Inorganic Chemicals (IOCs)", to read as follows:

APPENDIX B TO SUBPART Q OF PART 141 – STANDARD HEALTH EFFECTS LANGUAGE FOR PUBLIC NOTIFICATION

Contaminant	MCLG[1] mg/L	MCL[2] mg/L	Standard health effects language for public notification
	* * *		
9. Arsenic[11]	0	0.010	Some people who drink water containing arsenic in excess of the MCL over many years could experience skin damage or problems with their circulatory system, and may have an increased risk of getting cancer.
	* * *		

Appendix B – Endnotes

1. MCLG – Maximum contaminant level goal.

2. MCL – Maximum contaminant level.

* * *

11. These arsenic values are effective January 23, 2006. Until then, the MCL is 0.05 mg/L and there is no MCLG.

* * *

(2)

SUPREME COURT FILED
AUG 9 - 2004
OFFICE OF THE CLERK

No. 03-1640

In the Supreme Court of the United States

STATE OF NEBRASKA, ET AL., PETITIONERS

v.

ENVIRONMENTAL PROTECTION AGENCY

ON PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE DISTRICT OF COLUMBIA CIRCUIT

BRIEF FOR THE RESPONDENT IN OPPOSITION

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QUESTION PRESENTED

Under the Safe Drinking Water Act, 42 U.S.C. 300f *et seq.*, the Environmental Protection Agency (EPA) is required to promulgate national standards for maximum contaminant levels (MCLs) in drinking water. In 2001, EPA published a final rule setting the MCL for arsenic at 0.01 milligrams per liter (mg/L). After notice and comment, EPA subsequently issued a clarification rule restating the specification of the MCL for arsenic as 0.010 mg/L. The question presented is as follows:

Whether EPA's clarification rule regarding the MCL for arsenic constitutes a valid exercise of the agency's authority to interpret its own regulations.

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In the Supreme Court of the United States

No. 03-1640

STATE OF NEBRASKA, ET AL., PETITIONERS

v.

ENVIRONMENTAL PROTECTION AGENCY

ON PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE DISTRICT OF COLUMBIA CIRCUIT

BRIEF FOR THE RESPONDENT IN OPPOSITION

OPINION BELOW

The opinion of the court of appeals (Pet. App. 1-3) is not published in the *Federal Reporter*, but is reprinted in 89 Fed. Appx. 277.

JURISDICTION

The court of appeals entered its judgment on March 8, 2004. The petition for a writ of certiorari was filed on June 4, 2004. The jurisdiction of this Court is invoked under 28 U.S.C. 1254(1).

STATEMENT

1. In 1974, Congress enacted the Safe Drinking Water Act (SDWA), 42 U.S.C. 300f *et seq.*, in order to "assure that water supply systems serving the public

meet minimum national standards for protection of public health." H.R. Rep. No. 1185, 93d Cong., 2d Sess. 1 (1974). Under the SDWA, the Environmental Protection Agency (EPA) is required to promulgate national standards for maximum contaminant levels (MCLs) of certain substances in public water supplies. 42 U.S.C. 300g-1(b). A State may assume "primary enforcement responsibility" over public water systems within its jurisdiction, provided that, *inter alia*, the State adopts regulations that are at least as stringent as EPA's national regulations. 42 U.S.C. 300g-2(a). When EPA promulgates a new national regulation, a "primacy" State (*i.e.*, a State that has assumed primary enforcement responsibility under the SDWA) has two years to adopt a conforming state regulation (unless EPA grants an extension). 42 U.S.C. 300g-2(a)(1).

In 1942, the Public Health Service had established a national standard for arsenic of 0.05 milligrams per liter (mg/L), or 50 micrograms per liter (µg/L). 65 Fed. Reg. 38,894 (2000).[1] Upon enactment of the SDWA, EPA issued an interim regulation establishing 0.05 mg/L as the MCL for arsenic. 40 C.F.R. 141.11(b).

2. In 1996, Congress amended the SDWA to require EPA to issue a new national standard for arsenic by January 1, 2001. Pub. L. No. 104-182, § 109, 110 Stat. 1627 (42 U.S.C. 300g-1(b)(12)(A)(v)). In response, EPA proposed a rule reducing the MCL for arsenic from 0.05 mg/L to 0.005 mg/L. 65 Fed. Reg. at 38,888. Pursuant

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[1] Quantities of contaminants are sometimes expressed in parts per million (ppm) and parts per billion (ppb). Because one liter of pure water weighs exactly one kilogram at a certain temperature and atmospheric pressure, 1 mg/L is treated as the equivalent of 1 ppm, and 1 µg/L is treated as the equivalent of 1 ppb. For the sake of simplicity, we will use primarily the metric measures (mg/L and µg/L) in this brief.

to the requirements of the SDWA, EPA engaged in notice-and-comment rulemaking with respect to the proposed new MCL, and performed a comprehensive risk and cost analysis. See 42 U.S.C. 300g-1(b)(3)(C), (b)(12)(A)(v) and (d). On January 22, 2001, EPA published its final rule, adopting a new MCL for arsenic of 0.01 mg/L. 66 Fed. Reg. 6976. Although EPA subsequently delayed the effective date of the rule pending further review, the rule ultimately took efect unchanged. *Id.* at 16,134, 28,342; C.A. App. 226.[2] Public water systems are required to comply with the new arsenic standard by January 23, 2006. 40 C.F.R. 141.60(b)(4).[3]

Consistent with the MCLs for other contaminants (which are expressed in milligrams per liter), EPA specified the MCL for arsenic in the relevant regulation as "0.01 mg/L." 40 C.F.R. 141.62(b)(16) (2002). In a separate regulation adopted at the same time as the new arsenic MCL, however, EPA required covered water systems to report their arsenic results "to the nearest 0.001 mg/L." 40 C.F.R. 141.23(*i*)(4). In its notice of proposed rulemaking, EPA suggested that this reporting requirement was designed to ensure that "values between 0.010 mg/L and 0.014 mg/L will be

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[2] Some of the petitioners in this action challenged EPA's final rule on Commerce Clause and Tenth Amendment grounds, claiming that the SDWA impermissibly regulated the intrastate distribution and sale of drinking water and impermissibly operated directly on the States. The D.C. Circuit denied the petition for review. *Nebraska* v. *EPA*, 331 F.3d 995 (2003).

[3] The SDWA requires EPA to review and revise, as appropriate, its national standards every six years. 42 U.S.C. 300g-1(b)(9). The next review of the arsenic standard is already ongoing and is scheduled to be completed by August 2008. 68 Fed. Reg. 14,503 (2003).

averaged to the nearest 0.001 mg/L," rather than rounded down to "one significant figure" (*i.e.*, 0.01 mg/L). 65 Fed. Reg. at 38,918-38,919. Moreover, in the preamble to the final rule, EPA stated that "the enforceable MCL is 0.01 mg/L, which is the same as 10 micrograms per liter (µg/L) or 10 parts per billion (ppb)." 66 Fed. Reg. at 6981. EPA noted in the opening paragraph of the preamble that it would thenceforth refer to the arsenic concentration in micrograms per liter (µg/L), *id.* at 6979, and proceeded to do so consistently in the detailed risk and cost analysis required by the SDWA, *e.g.*, *id.* at 7010-7020. And in its official guidance concerning the new rule, EPA cited the arsenic reporting regulation for the proposition that it had "clearly intended 10 ppb (0.010 mg/L) to be used for determining compliance." C.A. App. 228.

3. After EPA's regulations took effect, some States and other affected entities expressed concern that, under the specified MCL of 0.01 mg/L, public water systems with arsenic levels as high as 14.9 µg/L (or 0.0149 mg/L) could round downward to 0.01 mg/L and thereby claim that they were in compliance with the regulations. See, *e.g.*, C.A. App. 429-430. Although EPA believed that the regulations unambiguously established that the MCL of 0.01 mg/L was identical to 10 µg/L (*i.e.*, 10 parts per billion), and thus precluded the type of rounding that had been suggested, EPA recognized that the specification of the MCL as 0.01 mg/L could lead to confusion and unnecessary transaction costs, especially in "primacy" States that were required to adopt new regulations of their own. 67 Fed. Reg. 78,205 (2002). Consequently, EPA proposed a clarification rule that restated the specification of the MCL for arsenic as 0.010 mg/L. *Id.* at 78,203. On

March 25, 2003, after notice and comment, EPA promulgated the clarification. 68 Fed. Reg. 14,502.

4. Petitioners, the State of Nebraska and various municipalities and public water systems, challenged EPA's clarification rule in the United States Court of Appeals for the District of Columbia Circuit under the SDWA's judicial-review provision. See 42 U.S.C. 300j-7(a). Petitioners contended, *inter alia*, that the clarification rule was invalid because EPA had failed to perform a comprehensive risk and cost analysis or meet other procedural requirements for rulemaking under the SDWA. See Pet. C.A. Br. 13-16; Pet. C.A. Reply Br. 3-6.

The court of appeals denied the petition for review in an unpublished *per curiam* order. Pet. App. 1-3. The court reasoned that "the EPA's decision to clarify the technical expression of the arsenic Maximum Contaminant Level (MCL) by adding an extra zero to the technical expression of the MCL as measured in mg/L does not alter the substance of the 10 parts per billion MCL established" in the original rule. *Id.* at 1. The court noted that EPA had consistently interpreted its regulations as establishing an MCL of 10 µg/L, and reasoned that EPA's interpretation of its own regulations was entitled to deference unless the interpretation was "plainly erroneous" or "inconsistent with the regulation." *Id.* at 2 (quoting *Auer* v. *Robbins*, 519 U.S. 452, 461 (1997)). The court concluded that the interpretation in this case was neither, and was therefore entitled to deference. *Ibid.*

The court of appeals rejected petitioners' reliance on a 1981 guidance document, which suggested that levels of contaminants need only be reported in a form containing the same number of significant digits as the MCL. Pet. App. 2. The court observed that, notwith-

standing the earlier guidance document, the reporting provision of the arsenic rule specifically required that arsenic levels be reported to the nearest 0.001 mg/L, and an example in the rule confirmed that arsenic levels were to be rounded to the nearest 0.001 mg/L. *Ibid.* The court therefore concluded that "the EPA's reference to its 1981 guidance document does not demonstrate the EPA promulgated a new arsenic MCL" in its clarification rule. *Ibid.*[4]

ARGUMENT

The decision of the court of appeals is correct and does not conflict with any decision of this Court. Further review is therefore not warranted.

1. The court of appeals correctly concluded that EPA's clarification rule is valid.

a. EPA's original rule unambiguously established an MCL of 10 µg/L. Although EPA did specify the MCL for arsenic in the relevant regulation as "0.01 mg/L," 40 C.F.R. 141.62(b)(16) (2002), EPA also required covered water systems to report their arsenic results to an extra significant digit, 40 C.F.R. 141.23(*i*)(4). Petitioners offer no explanation why EPA would have required covered water systems to *report* their arsenic results to the nearest 0.001 mg/L if those systems could *comply* with the MCL for arsenic simply by rounding downward to the nearest 0.01 mg/L. Moreover, although EPA specified the MCL for arsenic in milligrams per liter (consistent with the MCLs for

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[4] The court of appeals summarily rejected petitioners' claims that EPA also violated the Unfunded Mandates Reform Act of 1995, 2 U.S.C. 1501 *et seq.*, and the Regulatory Flexibility Act, 5 U.S.C. 601 *et seq.*, in promulgating the clarification rule. Pet. App. 2-3. Petitioners do not pursue those claims in the petition.

other contaminants), the preamble to the rule expressly equates 0.01 mg/L with 10 µg/L, 66 Fed. Reg. at 6981, and is replete with references to "a final MCL of 10 µg/L," *e.g.*, *id.* at 7020. Indeed, the risk and cost analysis contained in the rule explicitly compares the risks and costs of an MCL of 10 µg/L with those of potential MCLs of 3, 5, and 20 µg/L. *E.g.*, *id.* at 7010-7020. In light of that analysis, it would be perverse to suggest that EPA, in its original rule, effectively adopted an MCL of 14.9 µg/L (as would ostensibly be the case if covered water systems were allowed to round downward to the nearest 0.01 mg/L).

b. Even assuming *arguendo* that EPA's original rule was ambiguous, moreover, petitioners effectively concede (Pet. 8) that EPA's subsequent interpretation of that rule was reasonable.[5] This Court has consistently held that an agency's interpretation of its own regulations is entitled to substantial deference. See, *e.g.*, *Washington State Dep't of Soc. & Health Servs.* v. *Guardianship Estate of Keffeler*, 537 U.S. 371, 387–388 (2003); *Barnhart* v. *Walton*, 535 U.S. 212, 217 (2002); *Auer* v. *Robbins*, 519 U.S. 452, 461 (1997).[6] Nothing in

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[5] At one point, petitioners do argue (Pet. 7) that EPA was changing, rather than interpreting, its original rule in promulgating its clarification rule. Petitioners, however, make no effort to establish the necessary premise to that argument: namely, that the original rule unambiguously established an MCL other than 10 µg/L.

[6] Petitioners seemingly contend (Pet. 7-8) that *Auer* does not provide a basis for deferring to an agency's interpretation of its own regulations. The portion of *Auer* on which petitioners rely, however, does not address the question whether an agency's interpretation of its own regulations is entitled to deference, but instead addresses the distinct, and threshold, question whether an agency's *regulation* interpreting a *statute* is entitled to deference. See 519 U.S. at 456-459. The language petitioners quote (Pet. 4, 6)

those decisions suggests that an agency must go through formal rulemaking in order to receive deference for its interpretation of its own regulations; to the contrary, in *Auer*, this Court deferred to an interpretation contained in an *amicus* brief filed by the agency in question. See 519 U.S. at 561. Assuming *arguendo* that EPA's original rule was ambiguous, therefore, EPA went beyond what was required by providing the opportunity for comment before issuing its clarification rule; indeed, EPA's clarification-rule did nothing more than codify an interpretation that EPA had already set out in its official guidance on the original rule. See C.A. App. 228.

2. Petitioners contend (Pet. 5-7) that EPA failed to comply with the statutory requirement that "[a]ny revision of a national primary drinking water regulation shall be promulgated in accordance with" the various procedural requirements of Section 300g-1(b)(9) of the SDWA. 42 U.S.C. 300g-1(b)(9). By its terms, however, that requirement is inapposite where EPA is not actually "revisi[ng]" an existing regulation by changing an unambiguous substantive requirement, but is at most merely clarifying an ambiguity in the regulation.[7] EPA and the court of appeals correctly concluded that no "revision" occurred here.

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from *FDA* v. *Brown & Williamson Tobacco Corp.*, 529 U.S. 120 (2000), is inapposite for the same reason.

[7] Under petitioners' plenary construction of the term "revision," EPA would apparently lack the authority even to correct typographical errors in its SDWA regulations without repeating every step originally undertaken to support the issuance of the regulations pursuant to the procedural requirements of Section 300g-1. EPA has recently exercised such authority. See 69 Fed. Reg. 38,850 (2004).

Finally, requiring EPA to perform a comprehensive risk and cost analysis and comply with the SDWA's other procedural requirements before issuing a clarification rule would be little more than an empty exercise in this case. In promulgating its original rule setting the MCL for arsenic at 0.01 mg/L, EPA expressly used an MCL of 10 µg/L in its risk and cost analysis. *E.g.*, 66 Fed. Reg. at 7010-7020. If petitioners were correct that a new risk and cost analysis was required, therefore, EPA could have satisfied that requirement simply by republishing its earlier risk and cost analysis together with the clarification rule. And to the extent that petitioners are implicitly seeking to raise substantive concerns about an MCL of 10 µg/L by forcing EPA to comply a second time with the SDWA's procedural requirements, petitioners had the opportunity to express those concerns in EPA's rulemaking process for the original rule, and indeed did so. See C.A. App. 295-311. In any event, because the court of appeals' unpublished decision is correct and does not conflict with any decisions of this Court, further review is unwarranted.

CONCLUSION

The petition for a writ of certiorari should be denied.

Respectfully submitted.

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